K082187

BIOMET SPINE

NOV 13 2008

# 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

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|---|---|
| **Preparation Date:** | November 11, 2008 |
| **Applicant/Sponsor:** | Biomet Spine<br>100 Interpace Parkway<br>Parsippany, NJ 07054 |
| **Contact Person:** | Vivian Kelly<br>Phone: 973-299-9300 x2214<br>Fax: 973-257-0232 |
| **Trade name:** | Biomet Lumbar Plate System |
| **Common Name:** | Lumbar spinal fixation system |
| **Classification Name -Product Code:** | Spinal intervertebral body fixation orthosis - KWQ |
| **Device Panel - Regulation No.:** | Orthopedic - 21 CFR 888.3060 |

**Device Description:**

The Biomet Anterior Lumbar Plate System consists of a titanium alloy plate and bone screws. The plates are available with two different lordotic curves for the lumbar or lumbosacral regions. Plates will be available in different lengths. The plates have threaded holes to accommodate bone screws, which will be available in different diameters and lengths.

**Indications for Use:**

The Anterior Lumbar Plate System is an anterior or antereolateral spinal fixation device indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels in the fusion of the lumbar or lumbosacral spine at levels L1 through S1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of solid spinal fusions in patients with degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis, spondyloysis, spondylolisthesis, stenosis and/or failed previous fusion.

**Summary of Technologies:**

The Biomet Anterior Lumbar Plate System has similar technologies to the predicate devices.

**Substantial Equivalence:**

The Biomet Lumbar Plate is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Example of predicates include Synthes Anterior Tension Band (ATB) System (K022791), Zimmer Trinica® Anterior Lumbar Plate System (K061353) and EBI's Top Loading MAS Spinal Fixation System (K033312).Based upon the mechanical testing, the Biomet Anterior Lumbar Plate is substantially equivalent for its intended use to other spinal systems currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 2008

EBI, L.P.
% Ms. Vivian Kelly, MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K082187
Trade/Device Name: Biomet Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis.
Regulatory Class: II
Product Code: KWQ
Dated: November 03, 2008
Received: November 05, 2008

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082187

Device Name: Biomet Anterior Lumbar Plate System

Indications for Use:

The Anterior Lumbar Plate System is an anterior or antereolateral spinal fixation device indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels in the fusion of the lumbar or lumbosacral spine at levels L1 through S1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of solid spinal fusions in patients with degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma including fractures, tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudoarthrosis, spondyloysis, spondylolisthesis, stenosis and/or failed previous fusion.

| Prescription Use **X** (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K082187